**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**WASHINGTON, D.C. 20460**

**OFFICE OF THE ADMINISTRATOR**
**EPA SCIENCE ADVISORY BOARD**

May 17, 2002

**MEMORANDUM**

SUBJECT: US EPA Science Advisory Board (SAB) Trichloroethylene Health Risk Assessment: Synthesis and Characterization Review Panel (TCE Review Panel) – Documentation for Panel Formation Determinations

FROM: Angela Nugent
Designated Federal Officer
Office of the EPA Science Advisory Board (1400A)

TO: Robert Flaak
Acting Director
Office of the EPA Science Advisory Board (1400A)

This memo addresses the set of determinations that are necessary for starting a review by the SAB. It provides background information on this SAB review activity and then addresses:

1) the charge developed for the panel;
2) the type of Panel that will be used to conduct the review, the name of the Panel, and identification of the Panel Chair; the types of expertise needed to address the charge;
3) identification of parties who are potentially interested in or may be affected by the topic to be reviewed;
4) whether the charge involves a Particular Matter and how conflict of interest regulations under 18 U.S.C. 208. apply to members of the panel;
5) how regulations concerning "appearance of lack of impartiality" under 5 C.F.R. 2635.502 apply to members of the panel;
6) how individuals were placed on the "Short List" posted on the SAB website as candidates for the panel; and
7) how individuals were placed on the final panel.

This memo serves to document the status of decisions on each of these topics and to document the OSAB Director's approval of those decisions.

## A. Background

The EPA Science Advisory Board was asked by the Office of Research and Development (ORD) to peer review a draft document "Trichloroethylene (TCE) Health Risk Assessment Synthesis and Characterization." A request for nominations for the peer review panel appeared in the *Federal Register* on October 30, 2001 (66 FR 54768-54769; See Attachment 1). In that *Federal Register* notice the Board noted that "TCE is a major contaminant of concern in EPA's air, water, and waste programs" and that the peer review draft was "published for public comment on September 19, 2001 at 66 FR 48257-48258. EPA's regulatory program and regional offices have identified TCE as among the highest priorities for a new assessment." ORD has informed the SAB that over 800 pages of public comment were received on the external review draft from 19 commenters.

ORD also informed the SAB that it had used a peer involvement process in developing the draft document. This peer involvement process had two components. First, ORD organized an "External Involvement Group," composed of nine representatives from private industrial organizations, public interest groups, academic research institutions and State and Federal Agencies. Their tasks were to (1) propose topics for state of the science papers and secure expert scientists as authors; (2) review those papers for balance and completeness; (3) propose topics for synthesis and characterization; (4) suggest peer reviewers; and (5) keep scientists from their sector informed. Second, ORD sponsored, with several other partners, 16 state-of-the-science papers by experts who conducted research related to the assessment of TCE's health risks. Those papers were published as a supplemental issue of *Environmental Health Perspectives* (Volume 108, supplement 2, May 2000). In the document the SAB was asked to review, EPA states that "Its conclusions draw from 16 state of the-science papers...these authors have individually provided many constructive comments and suggestions for this synthesis and characterization, but were not asked for consensus on its overall conclusion.."[1]

## B. Determinations

1) <u>The charge to the panel</u>: SAB Staff, the Chair of the SAB's Environmental Health Committee, and the Agency negotiated the following charge:

(a) Does the assessment adequately discuss the likelihood that

[1]USEPA, *Trichloroethylene Health Risk Assessment: Synthesis and Characterization*, EPA/600P-01/002A, August 2001, External Review Draft, pp. x1-x11.

trichloroethylene (TCE) acts through multiple metabolites and multiple modes of action?

(b) Is the cancer weight-of-evidence characterization adequately supported?

(c) A new feature of the cancer database is molecular information on the von Hippel-Lindau tumor suppressor gene. Is this information adequately discussed and are the conclusions appropriate?

(d) Does the assessment adequately discuss the use of multiple critical effects in developing an oral reference dose (RfD) and inhalation reference concentration (RfC) for effects other than cancer? Are the uncertainty factors well discussed and well supported?

(e) Does the assessment adequately discuss the derivation of a range of estimates for the cancer risk? Are there any studies that should/should not have been included?

(f) Please comment on the use of calibrated models and uncertainty analysis to address the question of pharmacokinetic model uncertainty.

(g) Is it appropriate to consider background exposures and other characteristics of an exposed population as modulating the risk of TCE exposure in that population?

(h) Do the data support identifying risk factors that may be associated with increased risks from TCE exposure? Are there any risk factors that should/should not have been included?

(i) Do the data support the possibility that TCE can affect children and adults differently? Should this be reflected in the quantitative assessment?

2) Type of Panel that will be used to conduct the review, the name of the Panel, and identification of the Panel Chair; types of expertise needed to address the charge: A panel of the SAB's Environmental Health Committee (EHC) called the "Trichloroethylene Health Risk Assessment: Synthesis and Characterization Review Panel (TCE Review Panel)" will conduct the review. The EHC Chair, Dr. Henry Anderson, will chair the panel. The EHC contains experts in various aspects of human health assessment and is the natural venue at the SAB for the TCE review. The SAB, in its October 2001 FR Notice cited above asked for additional experts to augment the EHC to address the draft TCE document. In the FR notice, the Board requested nominations in the following areas: risk assessment and the application of the Agency's risk assessment guidelines; toxicology including carcinogenicity, with a focus on mechanisms of action and pharmacokinetic models; and molecular genetics.

3) Identification of parties who are potentially interested in or may be affected by the topic to be reviewed: Entities involved in Superfund clean-ups, U.S. Air Force bases where solvents are used to clean engines; solvent manufacturers, chemical manufacturers who use TCE in manufacture of other chemicals; companies that use TCE for de-greasing machinery; and water suppliers who deal with TCE in their water.

Other interested parties are those who follow risk assessment developments, because they see TCE as a precedent for EPA's implementation of new risk assessment approaches

4) Whether the charge involves a Particular Matter[2] and how conflict of interest regulations apply to members of the panel: The SAB panel's activity in addressing the charge does qualify as a particular matter because the advice that will result will be part of a deliberation, in that the Federal Expert or Special Government Employee (SGE), who are serving on the panel, will be providing advice that will be considered in the course of the Agency's deliberation about the risk characterization of TCE, information that will factor into EPA's regulatory decisions. Although the review however, does not focus on interests of specific people (i.e., it is not a "specific party matter"), it does arguably focus on the interest of a discrete and identifiable class of people, i.e., those who make or use the chemical (such as certain chemical companies and those who use the material for de-greasing) and those who are involved in situations in which TCE has polluted soil or ground water.

In order to determine how conflict of interest regulations apply to members of the panel, the DFO conducted an analysis for each panel member to determine whether the following provision of 18 U.S.C. 208 applies: "An employee is prohibiting from participating personally and substantially in an official capacity in any particular matter in which he, to his knowledge, he or any person whose interests are imputed to him under this statute has a financial interest, if the particular matter will have a direct and predictable effect on that interest."

For this review, the DFO assumes generally that the panel members will be participating personally in the review and that they will be participating substantially. Following standard procedures, the DFO determines, on a case-by-case basis whether the panel member knows of any financial interest in this matter on the part of the SGE; the SGE's spouse or minor child; a general partner; an organization in which the SGE is serving as an officer, director, trustee, general partner, or employee; or a prospective employer. The DFO has determined through review of all Confidential Financial Disclosure Reports provided by all prospective panelists that there is no conflict of interest presented.

The DFO assumes generally for this review that the panel's advice on the particular matter under review will not have a direct effect on the financial interest of panelists.[3] The

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[2]The term "particular matter" refers to matters that involve deliberation, decision, or action that is focused on the interests of specific people or a discrete and identifiable class of people. The term may include matters that do not involve formal parties and may extend to legislation or policy-making that is narrowly focused on the interests of a discrete and identifiable class of people. But the term does not cover consideration or adoption of broad policy options directed to the interests of a large and diverse group of people. [5 C.F.R. 2640.103(a)(1)]

[3]A particular matter has a direct effect on a financial interest if a close causal link exists between any decision/action to be taken in the matter and any expected effect of the matter on the financial interest. An effect may be direct even though it does not occur immediately. A particular matter does not have a direct effect on a financial interest, however, if the chain of causation is attenuated or is contingent upon the occurrence of events that are speculative or that are independent of, and unrelated to, the matter. A particular matter that has an effect on a financial interest only as a consequence of its effects on the general economy is not considered to have a direct effect. 5 C.F.R. 2640.103(a)(3)(i).

rationale is that the SAB in this review is simply giving advice. Its opinions will be considered by the Agency, in combination with advice from other sources and with considerations on different factors than the technical factors being considered by the Board. It would be speculative to anticipate what the effect of the SAB's advice on this matter would be.

5. How regulations concerning "appearance of lack of impartiality" under 5 C.F.R. 2635.502 apply to members of the panel. The Code of Federal Regulations state that "Where an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his household, or knows that a person with whom he has a covered relationship is or represents a party to such matter, and where the person determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his impartiality in the matter, the employee should not participate in the matter unless he has informed the agency designee of the appearance problem and received authorization from the agency designee."

The TCE review activity is not a specific party matter, so there is no legal issue concerning "appearance of lack of impartiality" under federal regulations.

6. How individuals were selected for the "Short List" posted on the SAB website as candidates for the panel. On May 6, 2002, the SAB Staff posted a notice on the SAB website inviting comment on Prospective Candidates for the TCE Review Panel (Attachment 2). That notice stated that SAB staff narrowed a "Widecast" list of over 85 candidates to a "Short List" of 22 candidates, based upon their expertise, interest, availability, and credentials. Several aspects of "credentials" in this Short List choice are important. SAB Staff selected individuals for the "Short List" based on their established credentials in the technical areas required for the review and described in the SAB *Federal Register* notice, and also took care to include individuals with knowledge of the risk assessment literature on the chemical under review, TCE, who had not previously been involved with the EPA assessment. SAB Staff defined "involvement"in this case as: no authorship of the document, collaboration with the authors, prior peer review, involvement in ORD's "External Involvement Group," authorship of the "state-of-the-science papers" published as a supplemental issue of *Environmental Health Perspectives*, on which the Agency drew, or authors of public comments provided to the Agency as part of the formal public comment on the draft document.

7. How individuals were selected for the final panel. The SAB received five sets of public comments in response to its request for "information, analysis, or documentation" that the Board should consider in making its selection of members of the panel. (Attachment 3 lists the names of groups and individuals submitting public comment). These requests were received by the time the public comment period closed on May 15, 2002.

SAB Staff considered this information along with: (a) the Confidential Financial Disclosure Forms completed by all Short List Candidates; (b) responses from Short List candidates to queries about their "points of view" and relationship to the review material to be

considered by the panel (Attachment 4); (c) *Curriculum Vitae* provided by candidates and supplementary materials provided by them; and (d) results of an independent Lexis-Nexis search conducted on all Short List panel members.

SAB Staff developed a proposed final panel list for the TCE Review Panel for discussion with the Chair of the Panel, Dr. Henry Anderson. The proposal was designed to augment the existing Environmental Health Committee to broaden the expertise on the panel in needed areas and provide breadth of viewpoints on issues key to the review. The proposal expanded the panel specifically in the area of TCE epidemiology; pharmacokinetic modeling; cancer toxicity biostatistics and modeling; modes of action at the molecular level; modes of action at the physiological level; differing perspectives on how the toxicology database of information on TCE can be understood; and risk assessment expertise.

The Acting SAB Staff Director, the DFO, and the Chair met by teleconference on May 16, 2002 to discuss the proposal, along with the public comments and other information gathered. The Chair supported and the Staff Director approved. The Staff Director instructed the DFO to contact panel members to begin work on the review. (Attachment 5--Roster of individuals selected for the Panel).

Concurred,

/s/ May 17, 2002

Robert Flaak Date
Acting Director
EPA Science Advisory Board Staff

Attachment 1: *Federal Register* Request for Nominations for the TCE panel on October 30, 2001 (66 FR, 54768-54769)
Attachment 2: Invitation for Comment on Prospective Candidates to the TCE Review Panel
Attachment 3: List of the Names of Groups and Individuals Submitting Public Comment on the TCE Short List
Attachment 4: Questions posted to Short List candidates about their "points of view" and relationship to the review material to be considered by the panel
Attachment 5: Roster of individuals selected for the Panel

# Attachment 1

ENVIRONMENTAL PROTECTION AGENCY

[FRL-7094-9]

EPA Science Advisory Board Environmental Health Committee Review of the Trichloroethylene (TCE) Health Risk Assessment Synthesis and Characterization Draft Document; Request for Nominations

ACTION: Request for nominations to the Environmental Health Committee (EHC) of the Environmental Protection Agency's (EPA) Science Advisory Board (SAB) for its review of the Agency's draft Trichloroethylene (TCE) Health Risk Assessment.

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SUMMARY: The U.S. Environmental Protection Agency Science Advisory Board (SAB) is announcing the formation of a Panel to review the Agency's draft Trichloroethylene (TCE) Health Risk Assessment. The SAB is soliciting nominations to augment the existing EHC to form this Panel. The EPA Science Advisory Board was established to provide independent scientific and technical advice, consultation, and recommendations to the EPA Administrator on the technical bases for EPA regulations. In this sense, the Board functions as a technical peer review panel.

Any interested person or organization may nominate qualified individuals for membership on the panel. Individuals should have expertise in one or more of the following areas: risk assessment and the application of the Agency's risk assessment guidelines; toxicology including carcinogenicity, with a focus on mechanisms of action and pharmacokinetic models; and molecular genetics. Nominees should be identified by name, occupation, position, address and telephone number. To be considered, all nominations must include a current resume providing the nominee's background, experience and qualifications.

Background

EPA's Office of Research and Development (ORD) has completed an external review draft assessing the health risks of trichloroethylene. TCE is a major contaminant of concern in EPA's air, water, and waste programs. This draft was published for public comment on September 19, 2001 at 66 FR 48257-48258. EPA's regulatory program and regional offices have identified TCE as among the highest priorities for a new assessment.

This assessment was also shaped by several new developments in risk assessment. The practice of risk assessment is evolving from a focus on one toxic effect of one pollutant in one environmental medium toward integrated assessments covering multiple effects and multiple media and incorporating information about mode of action, uncertainty, human variation, and cumulative effects of multiple pollutants in different media. This evolution responds to recommendations of the National Research Council, which have been embraced in EPA's proposed cancer guidelines.

This draft assessment takes on the new directions in risk

assessment that EPA and others have advocated. The assessment discusses the possibility that children, infants, and the developing fetus may differ from adults with respect to susceptibility to TCE's toxic effects. The assessment addresses cumulative risks by discussing the implications of other chlorinated solvents and agents that have metabolic pathways, potential modes of action, and toxic effects similar to TCE. The assessment implements principles of the proposed cancer guidelines by emphasizing characterization discussions, using mode-of-action information, and identifying susceptible populations.

The issues surrounding TCE are quite complex, with extensive information in some areas and relatively little information in others. The ORD initiated development of 16 peer-reviewed state-of-the-science papers that were published in Environmental Health Perspectives (vol. 108, suppl. 2, May 2000). These papers, which provide the primary scientific support for the assessment, were written by well-recognized scientists carrying out research on TCE or its metabolites.

To accomplish this review, the Science Advisory Board (SAB) will convene a Panel to address the following draft Charge:

(a) Does the assessment adequately discuss the likelihood that trichloroethylene (TCE) acts through multiple metabolites and multiple modes of action?

(b) Is the cancer weight-of-evidence characterization adequately supported?

(c) A new feature of the cancer database is molecular information on the von Hippel-Lindau tumor suppressor gene. Is this information adequately discussed and are the conclusions appropriate?

(d) Does the assessment adequately discuss the use of multiple critical effects in developing an oral reference dose (RfD) and inhalation reference concentration (RfC) for effects other than cancer? Are the uncertainty factors well discussed and well supported?

(e) Does the assessment adequately discuss the derivation of a range of estimates for the cancer risk? Are there any studies that should/should not have been included?

(f) Please comment on the use of calibrated models and uncertainty analysis to address the question of pharmacokinetic model uncertainty.

(g) Is it appropriate to consider background exposures and other characteristics of an exposed population as modulating the risk of TCE exposure in that population?

(h) Do the data support identifying risk factors that may be associated with increased risks from TCE exposure? Are there any risk factors that should/should not have been included?

(i) Do the data support the possibility that TCE can affect children and adults differently? Should this be reflected in the quantitative assessment?

The criteria for selecting Panel members are that these persons be recognized experts in their fields; that they be as impartial and objective as possible; that they represent an array of backgrounds and perspectives (within their disciplines); and that they be available to participate fully in the review, which will be conducted over a relatively short time frame (i.e., within approximately four months). Panel members will be asked to attend at least one public meeting followed by at least one public telephone conference meeting over the course of four months; they will be asked to participate in the discussion of key issues and assumptions at these meetings, and they will be asked to review and to help finalize the products and outputs of the panel. The panel will make recommendations to the Executive Committee (EC) of the SAB for approval of the Board's report and

transmittal to the Administrator.

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Nominations should be submitted to Mr. Samuel Rondberg, Designated Federal Officer, EPA Science Advisory Board via e-mail to Rondberg.Sam@epamail.epa.gov followed by ``hard copy'' via U.S. mail addressed to Mr. Samuel Rondberg, Designated Federal Officer, EPA Science Advisory Board (1400A), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, telephone (301) 812-2560, no later than November 9, 2001. The Agency will not formally acknowledge or respond to nominations.

General Information

Additional information concerning the EPA Science Advisory Board, its structure, function, and composition, may be found on the SAB Web site (<A HREF="http://www.epa.gov/sab">http://www.epa.gov/sab</A>) and in the Science Advisory Board FY2000
Annual Staff Report which is available from the SAB Publications Staff at (202) 564-4533 or via fax at (202) 501-0256.

Dated: October 22, 2001.
Donald G. Barnes,
Staff Director, Science Advisory Board.
[FR Doc. 01-27285 Filed 10-29-01; 8:45 am]
BILLING CODE 6560-50-P

Attachment 2

Invitation for Comment on Prospective Candidates to the US EPA Science Advisory Board (SAB) Trichloroethylene Health Risk Assessment: Synthesis and Characterization Review Panel (TCE Review Panel):

The SAB announced in the October 30, 2001 Federal Register (Volume 66, Number 2101, pages 54768-54769) that it has been asked to undertake a review of an Agency document entitled *Trichlorethylene Health Risk Assessment: Synthesis and Characterization*, Draft Report, prepared for the U.S. Environmental Protection Agency, Office of Research and Development, EPA/600/P-01/002A, August 2001 External Review Draft. The EPA Science Advisory Board (SAB) in that Federal Register notice invited nominations for consideration on the review panel being formed.

The SAB's process for panel formation has been designed for three purposes: to help the Board meet EPA's legal requirements; to be transparent to the public, so the public can understand and participate in the process; and to help the Board fulfill its mission. Over 85 persons were identified as potential members of this panel. SAB staff have now narrowed the list to a "Short List" of 22 candidates, based upon their interest, availability, credentials, and expertise needed. From these 22 individuals, approximately 12-15 panelists will be selected for this review. Eight of the 22 nominees are current members of the SAB's Environmental Health Committee. The background for the review and charge to the panel appeared in the October 30, 2001 Federal Register. This notice is available on this SAB website for reference, and therefore is not repeated here.

Brief biosketches of the 22 candidates on the current "Short List" are listed below for public comment. We invite comments from the public to provide the Board with information, analysis, or documentation that the Board should consider in evaluating the remaining candidates. This information will be carefully considered in determining the panel members chosen during the "Panel Selection" Phase.

The SAB Staff Director, in consultation with SAB leadership, as appropriate, makes the final decision about who will serve on the panel in the "Panel Selection" phase. In that phase, SAB Staff completes its review of information regarding conflict of interest, possible appearance of impartiality, and appropriate balance and breadth needed to address the charge. They review all the information provided by the candidates, along with any information that the public may provide in response to the posting of information about the prospective panel on the SAB website during the "Short List Phase," and information gathered by SAB Staff independently on the background of each candidate.

Please provide any advice, observations or comments you might think would be helpful in selecting the final candidates no later than May 15, 2002. Please make your comments to the attention of Dr. Angela Nugent, Designated Federal Officer, TCE Review Panel, U.S. EPA Science Advisory Board (1400A), 1200 Pennsylvania Avenue, NW, Washington, DC 20460. E-mailing comments (nugent.angela@epa.gov) is the preferred mode of receipt. We intend to make final selections no later than May 17, 2002.

The dates for the meetings on this topic will be formally announced in the Federal Register. They include a public teleconference on June 5, 2002 from 1:00 pm to 3:00 pm Eastern Standard Time to discuss the charge and the adequacy of the review materials to assist the Panel in answering the charge; a face-to-face review meeting in Washington, DC on June 18 and June 19, 2002.; and a contingency Conference Call to wrap up edits on July 22, 2002 from 1:00 p.m. to 3:00 p.m. Eastern Standard Time.

**Biosketches of "Short List" Candidates for the TCE Review Panel.**

Anderson, Henry: Wisconsin Division of Public Health, Proposed Chair of the TCE Review Panel and Current Chair of the SAB's Environmental Health Committee. Also a current member of the SAB Executive Committee.

In 1980 Dr. Anderson joined the Wisconsin Department of Health and Social Services as the State Environmental and Occupational Disease Epidemiologist. In 1991 he also assumed the duties of Chief Medical Officer. Among his duties for the State of Wisconsin has been the development of the scientific support documents for Wisconsin's Groundwater Enforcement Standards. One standard promulgated was for TCE. He was also responsible for state fact sheets on TCE in air and at hazardous waste sites.

He received his MD degree in 1972 and entered an Internal Medicine internship and then an occupational medicine residency. He was certified in 1977 by the American Board of Preventive Medicine with a sub-specialty in occupational and environmental medicine and in 1983 became a fellow of the American College of Epidemiology. He holds adjunct Professorships at the University of Wisconsin - Madison, Department of Preventive Medicine and the University of Wisconsin Institute for Environmental Studies, Center for Human Studies. He has published over 160 scientific articles on a broad spectrum of environmental, occupational and public health topics. He is principal investigator on nine active grants and cooperative agreements from federal government agencies including the U.S. EPA. None of these focus upon TCE, although the ATSDR Superfund Site Assessment Cooperative Agreement has evaluated sites contaminated with TCE and conducted exposure assessments.

His US EPA funded research grants address children's health issues, such as reproductive and endocrine function of frequent Great Lakes sport fish consumers and evaluation of women's awareness of mercury toxicity and sport fish consumption advisories. Other current research includes, childhood asthma, lead poisoning, arsenic in drinking water, youth occupational health, occupational fatalities and bioterrorism response. His expertise includes public health, preventive, environmental and occupational medicine, respiratory diseases, epidemiology, human health risk assessment and risk communication.

He was a founding member of the Agency for Toxic Substances and Disease Registry (ATSDR) Board of Scientific Councilors (1988-1992). He served on National Academy of Sciences/Institute of Medicine (NAS/IOM) committees that developed the reports "Injury in America" and "Nursing, Health & Environment." He was a member of the Armed Forces Epidemiology Board. He is current chair of the Environmental Health Committee of the USEPA Science Advisory Board and past chair of the SAB Integrated Human Exposures Committee. He serves on the USEPA SAB Executive Committee. He serves on several other FACA committees including the Director's Advisory Board for the National Center for Environmental Health, Centers for Disease Control and Prevention, the Hanford Health Effects Subcommittee for

ATSDR and is a member of the NIOSH Advisory Board on Radiation and Worker Health. He is a fellow of the Collegium Ramazzini and the American Association for the Advancement of Science. He is associate editor of the *American Journal of Industrial Medicine* and serves on the editorial board of *Cancer Prevention International*.

Blair, Aaron: National Cancer Institute, National Institute of Health

Dr. Blair is Chief of the Occupational Epidemiology Branch of the Division of Cancer Epidemiology and Genetics, National Cancer Institute. His research has focused on cancer risks from agricultural exposures, industrial chemicals, physical inactivity, occupational exposures among women, and methodolologic issues in occupational epidemiology. He has over 250 publications. He has evaluated the risk of non-Hodgkin's lymphoma, leukemia, and multiple myeloma among farmers in the first case-control studies to obtain detailed information on pesticide used and application practices. This work has culminated the development of the Agricultural Health Study, a long-term prospective study of 90,000 farmers and their spouses in Iowa and North Carolina. His studies of cancer mortality among workers exposed to the important industrial chemicals formaldehyde and acrylonitrile were among the first to employ sophisticated algorithms to develop quantitative estimates of exposure in multi-company studies. He has evaluated cancer risks among women in studies of dry cleaners and aircraft maintenance workers, who have significant exposures to various organic solvents including tetrachloroethylene and trichloroethylene. Methodologic studies have focused on confounding, meta-analysis, and misclassification in exposure assessment.

Dr. Blair has served on: IARC Monograph Working Groups; Environmental Protection Science Advisory Panel Subgroup on Atrazine; Federal Panel on Formaldehyde; National Center for Toxicologic Research Consensus Conference on Formaldehyde; IARC Workshop on Priorities for Epidemiologic Studies on Occupational Cancer; Advisory Committee to Trans-Canadian Study of Lymphatic and Hematopoietic Cancers; Task Force on Environmental Cancer and Heart and Lung Disease; Advisory Panel to Bureau of Chronic Disease, Health and Welfare, Canada on Future Research Directions; Farmers Study Advisory Committee, Health and Welfare, Canada; Advisory Group for Canadian Environmental Health Survey, Health and Welfare, Canada; NIH Inter-Institute Breast Cancer Working Group; Science Advisory Committee for the Lower Mississippi River Interagency Cancer Study; Louisiana State University Medical School; DHHS Environmental Health Policy Committee Subcommittee of Data Needs; Expert Panel on Domestic Use of Pesticides, National Cancer Institute of Canada; NCI Program Review Group on Leukemia, Lymphoma, and Multiple Myeloma; Cancer Research Methods Team; National Occupational Research Agenda, NIOSH; NCI Intramural Advisory Board; National Toxicology Board of Scientific Counselors; and on Organizing Committees for Conferences on Assessment of Smoking in Occupational Studies, Exposure Assessment in Occupational Investigations, and Physical Activity and Cancer.

He has served on Editorial Boards of the *American Journal of Epidemiology*, *Scandinavian Journal of Work, Environment and Health*, and the *Journal of Agricultural Safety and Health*. Dr. Blair is a member of the American Epidemiologic Society and a Fellow and Board Member of the American College of Epidemiology.

Academic Degrees: B.A., Kansas Wesleyan University 1965 Biology; M.S. North Carolina State University, 1967, Botany; Ph.D .North Carolina State University, 1970, Genetics;

M.P.H., University of North Carolina, 1976, Epidemiology.

Borghoff, Susan J.: CIIT Centers for Health Research

Dr. Susan Borghoff has been a Staff Scientist at CIIT Centers for Health Research in the Research Triangle Park, North Carolina since 1989 following her postdoctoral fellowship. Prior to her position at CIIT, Dr. Borghoff was a graduate student at the University of North Carolina and conducted her research at the National Institute for Environmental Health Sciences (NIEHS). Along with Dr. Borghoff's research program at CIIT she is also the Director of Education Programs which involves oversight of the pre- to post- graduate training programs and K-12 educational outreach activities.

Her research interests have focused on understanding the mode-of-action by which specific chemicals cause kidney toxicity and cancer in rats with a view to understanding the relevance of this response for human risk assessment. Her research has also focused on understanding the metabolism and pharmacokinetics of various chemicals with emphasis on the development of physiologically based pharmacokinetic models that can be used for risk assessment.

Currently Dr. Borghoff's research is focused on the developmental pharmacokinetics of estrogen-like compounds such as genistein. CIIT Centers for Health Research is a not-for-profit research institution in which the major core funding is a grant from the American Chemistry Council Long-Range Research Initiative. Other financial support comes from government agencies (U.S. Environmental Protection Agency (USEPA) and NIEHS), independent research organizations, trade associations, and corporations.

Dr. Borghoff's research projects have been funded both by the Core research program at CIIT and through specific research grants from Oxygenated Fuels Association, American Petroleum Institute, American Chemistry Council and ARCO (now Lyondell) Chemical Company. Dr. Borghoff received the Frank R. Blood Award in 1994 for the best paper of the year published in one of the Society of Toxicology research journals and a Society of Toxicology Risk Assessment Specialty Section Award in 2000.

She is a member of the North Carolina Chapter of the Society of Toxicology and the National Society of Toxicology in which she serves on the member of the program committee and most recently has been elected to serve on the Awards committee. She is currently on the editorial board for Toxicological Sciences and Chemical Biological Interactions.

Dr. Borghoff has served on review panels and as a working group member for national as well as international organizations that include the USEPA, National Cancer Institute, International Programme on Chemical Safety, European Centre for Ecotoxicology and Toxicology of Chemicals, and the International Agency for Cancer Research. She has also been a reviewer for the NIEHS Superfund Basic Research Program Grant (1999) and the Research Grants for the USEPA on Children's Health Issues (1999). Dr. Borghoff received her Ph.D. and M.S.P.H. in Environmental Sciences and Engineering from the University of North Carolina, and a B.S. in Chemistry from East Stroudsburg University in Pennsylvania. Dr. Borghoff became a Diplomat of the American Board of Toxicology in 1994.

Charnley, Gail: HealthRisk Strategies

Dr. Gail Charnley is an internationally recognized expert in environmental health risk assessment and risk management science and policy. She has over 20 years of experience in environmental toxicology, human health risk assessment, and risk management. As a consultant, she develops scientific, regulatory, and risk communication strategies to help clients respond to legal, regulatory, and public perception challenges in the United States and Europe. She also frequently serves on or chairs peer-review panels evaluating federal risk assessment methodologies or chemical-specific assessments of risk.

Her clients include companies, trade associations, law firms, non-profit organizations, and the federal government. During its tenure, she was executive director of the Presidential/Congressional Commission on Risk Assessment and Risk Management, mandated by Congress to evaluate the role that risk assessment and risk management play in federal regulatory programs. Before her appointment to the Commission, she served as acting director of the Toxicology and Risk Assessment Program at the National Academy of Sciences/National Research Council. She has been the project director for several National Academy of Sciences committees, including the Committee on Risk Assessment Methodology and the Complex Mixtures Committee, and served as the chair of several U.S. Army Science Advisory Board committees that evaluated health risk assessment practices in the Army.

She lectures frequently on risk science policy issues and is the author of numerous reports evaluating the toxicity of chemical exposures and their potential impact on public health as well as on risk management and democratic environmental decision-making.

Dr. Charnley is a past-president of the international Society for Risk Analysis, for which she has also served as counselor and chair of the Public Policy Committee. She has an adjunct faculty position at the Harvard School of Public Health and was recently appointed to the National Toxicology Program's Report on Carcinogens Committee. She holds a Ph.D. in Toxicology from M.I.T. and an A.B. in biochemistry from Wellesley College.

Edler, Lutz: German Cancer Research Center

Dr. Edler is the Head of Biostatistics at the Research Programme Genome Research and Bioinformatics of the German Cancer Research Center in Heidelberg Germany. He holds a Dipl. Math (M.S.) Mathematics, Physics from the Albert-Ludwigs-University, Freiburg, FRG and a Dr. rer. nat (Ph.D.) Mathematics from Johannes-Gutenberg-University, Mainz, FRG. His major areas of research are: Mathematical-statistical modeling of carcinogenesis and risk assessment; Pharmacokinetics and development of methodology for clinical oncology with a strong emphasis on the application computational statistics; Statistical Computing; Biostatistical Methods in Design and Analysis of Experiments; Mathematical and Statistical Modeling in Oncology; and Survival Analysis and Clinical Trials.

From 1990-1991 he was a Visiting Scientist, National Institute of Environmental Health Sciences, Division of Biometry and Risk Assessment, Research Triangle Park, U.S.A..

He has listed the following "Expert Meetings" in which he has participated: (1994) DAAD, Bad Godesberg; (1994) Human PBPK Models for TCDD, NIEHS, Research Triangle Park, USA; (1994, 1998) EUROSTAT, Luxembourg; (1998) Risk Assessment of Electromagnetic Waves, US NIEHS, Tucson, AZ, USA; (2000) Risk Assessment of Dioxin, US EPA, Fort Collins, USA; 5th Framework Program, EU, Brussels; (1998) Rapporteur at EMF Science Review Symposium of the NIEHS, Phoenix, AZ; and (2002) Working Group of

US-Vietnam Scientific Conference on Human Health and Environmental Effects of Agent Orange/Dioxins, March 2002, Hanoi, Rep Vietnam.

He is a member of the following professional societies: American Statistical Association (ASA); Drug Information Association (DIA); International Biometric Society, German Region (IBS.DR); International Society for Clinical Biostatistics (ISCB); International Association for Statistical Computing (IASC); Bernoulli Society; Deutsche Krebsgesellschaft (DKG); Gesellschaft fuer Medizinische Dokumentation und Statistik (gmds); and International Statistical Institute (ISI, elected).

Professional Activities include: (1991-1995) Scientific Secretary International Association for Statistical Computing (IASC); (1995-1997) Vice President of the International Association for Statistical Computing (IASC); (1999 -2001) President of the International Association for Statistical Computing (IASC); (1993-1997) Member of the Council of the German Region International Biometric Society; (1998-2002) Member of the Council of the International Biometric Society; and (1993- now) Member of the Animal Protection Commission at the RegPr. Karlsruhe. Currently he is 2002 Co-Organizer of the Session `Clinical Trial" at the International Biometric Conference, Freiburg, Germany; 2002 Coorganizer of the Session `Pharmacogenetics and Pharmacogenomics Data Analysis Methods in Future Clinical Trials', 38th DIA Annual Meeting, Chicago; 2003 Chair of the International Organizing Committee of the International Conference on Carcinogenesis Risk Assessment (ICCRA), Athens, Greece; and 2004 Co-Chair of the Local Organizing Committee of the Biometrical Colloquium of the German Region of the International Biometric Society, Heidelberg, Germany.

His grants include: (Feb. 1991) Visitor at the Universidad Nacional de Colombia at Bogota, Columbia; (1990) DFG Travel Grant for 48th Session of the ISI in Cairo, Egypt; (June, 1993) DAAD Travel Grant for a visiting lectureship in Columbia; (1995) DFG Travel Grant for 50th Session of the ISI in Beijing, China; (Sep-Dec 1995) Consulting National Institute of Statistical Sciences (NISS), Res.Triangle Park; and (Aug-Sep 2001) KOSEF-DFG Visiting Scientist Grant, Yonsei University, Seoul, South-Korea.

He serves on the following committees and Advisory Boards: Advisor for the Collaborative Project on Knowledgebased Systems in Medicine; Reviewer for the Government Department of Research and Technology Funding Programme; Reviewer for the DFG; - Extramural Review Board of the AIO (German Cancer Society); Project Assessment Committee of the Phase I/II Study Group of the AIO; Independent Safety Committee for Boehringer Mannheim Co.; and Reviewer for the German Cancer Society and Krebshilfe.

Currently his editorial tasks include: (since 1993) Associate Editor of Computational Statistics and Data Analysis (CSDA) and Associate Editor of ONKOLOGIE; (since 1994) Associate Editor of the Biometrical Journal (Biometrische Zeitschrift); (since 1999) Associate Editor of Journal of Cancer Research and Clinical Oncology; and (since 2002) Editor of the Virtual Online Journal "Biostatistics" (Elsevier, Publ.)

El-Masri, Hisham: Agency for Toxic Substance and Disease Registry

Dr. El-Masri obtained his Ph.D. in Environmental Health from the Colorado State University. He received his M.S. in Environmental Engineering from the California State University at Long Beach in Environmental Engineering. He obtained his B.S. Engineering from Kuwait University. As a post-doctoral fellow at the Colorado State University, he studied

the toxicity and pharmacokinetics of several environmental chemicals. As a staff scientist at the National Institutes of Environmental Health Sciences (NIEHS), Dr. El-Masri developed physiologically based pharmacokinetic (PBPK) models for several important environmental chemicals.

Dr. El-Masri is currently working as an Environmental Health Scientist in the Research Implementation Branch, Division of Toxicology, Agency for Toxic Substances and Disease Registry (ATSDR), Atlanta, GA, USA. He chairs the ATSDR Computational Toxicology Laboratory and directs research and computational activities that include development and application of PBPK, Bench Mark Dose (BMD) and quantitative structure activity relationship (QSAR) models. The computational laboratory supports ATSDR needs in characterizing risks to the public posed by environmental chemicals, particularly for those chemicals that lack appropriate experimental data or in emergency exposure scenarios.

His area of research focuses on risk assessment with emphasis on the development and application of mathematical and statistical biologically based models such as PBPK/PD models. He published models describing the pharmacokinetic interactions between trichloroethylene and 1,1-dichloroethylene, and the pharmacodynamic the interactions between carbon tetrachloride and kepone. He also developed a detailed biological model, which described several biochemical pathways, which primes hepatocytes to start replicating. He had been on several EPA and NIEHS committees dealing with risk assessment of chemical mixtures, cumulative risk analysis, and mathematical modeling approaches.

Foster, Paul: Independent Consultant (Current member, SAB Environmental Health Committee)

Paul Foster is currently an independent consultant in toxicology and risk assessment. Until February of 2002, he was the Director of the research program in Endocrine, Reproductive and Developmental Toxicology at the CIIT Centers for Health Research (a 501(c)(6) not for profit research institute) in Research Triangle Park, NC. He joined the Institute in December 1995 after a 13-year career at Zeneca's (formerly Imperial Chemical Industries and now Syngenta) Central Toxicology Laboratory in Cheshire, England, where he was Head of Reproductive and Developmental Toxicology. Dr Foster holds a PhD in biochemistry/ toxicology from Brunel University, Uxbridge UK and conducted his postdoctoral work at the National Foundation for Cancer Research laboratories in the UK.

Dr. Foster's research interests span from understanding the potential human health effects of endocrine disruptors; mechanisms of testicular toxicity; the study of early testicular Leydig cell dysfunction induced by chemicals as a prelude to hyperplasia and tumors; the use of rat whole embryo culture techniques for the study of structure - activity (developmental toxicity) relationships; and toxicokinetic and dynamic parameters affecting the induction of developmental toxicity.

Dr. Foster has served on numerous national and international committees dealing with reproductive toxicology and endocrine disruption. These have included: Environmental Protection Agency [*ad hoc* reviewer of internal research; SAP/SAB on endocrine disruptor research (EDSTAC)]; Environmental Protection Agency, Science Advisory Board, Environmental Health Committee; Expert consultant to National Advisory Council for Environmental Policy and Technology; Endocrine Disruptor Methods Validation SubCommittee.; National Research Council Committee on Toxicology; National Research

Council Sub-Committee on evaluation of reproductive and developmental toxicants; National Research Council Sub-Committee on evaluation of Di-(isopropyl) methyl phosphonate; expert reviewer for the Center for Evaluation of Human Reproductive Risks, NIEHS/ NTP; IPCS/ OECD workshop on reproductive risk assessment; OECD workshop on reproductive and developmental toxicity testing guidelines; IPCS/ WHO Environmental health criteria for Boron. IPCS/ WHO committee on the assessment of reproductive and developmental toxicity; IPCS/ WHO expert committee on endocrine disruptors; and European Commission evaluation of endocrine disruptors.

He is a member of a number of learned Societies dealing with toxicology and reproduction and is a former Chair of the Continuing Education Committee and Past President of the Reproductive and Developmental Toxicology specialty section of the Society of Toxicology. Dr. Foster is currently serving on the editorial board of *Reproductive Toxicology* and as an Associate Editor of *Toxicological Sciences*. Dr. Foster's research at the CIIT Centers for Health Research was supported by an Institute grant by the American Chemistry Council, Three of his post doctoral fellows received National Research Service Awards from NIEHS.

Greer, Linda: Natural Resources Defense Council (Current Member, SAB Executive Committee)

Dr. Greer is a senior scientist with the Natural Resources Defense Council, where she directs the Environment and Health program. She has a PhD in environmental toxicology, an M.S.P.H. in environmental science and engineering, and a BS in Biology. Her academic research focused on biodegradation of pesticides in soil and had a microbiology and chemistry focus. Linda has worked for almost 20 years for the public interest community, and her on-the-job expertise concerns a wide variety of toxic chemical issues, including familiarity with EPA policies on regulating carcinogens, quantifying exposures to toxics, and similar, along with familiarity on a wide range of EPA decisionmaking on specific toxic chemicals. She is also experienced in pollution prevention.

Dr. Greer also has taught a summer school course at Vermont Law School for nearly a decade on toxic chemicals. She currently serves on the Executive Committee of the Science Advisory Board as well as the National Academy of Sciences National Research Council Board on Life Sciences.

She receives significant support from the Beldon Fund, the Goldman Fund, and the Bauman Foundation and in the recent past also received support from the New York Community Trust, the Joyce Foundation, and the Pew Charitable Trusts. Several small similar philanthropic organizations also support her work. Dr. Greer also received a grant from EPA and DOE in the mid and late 1990's for a collaborative project with the Dow Chemical Company on pollution prevention opportunities at their Midland, Michigan plant. Neither Dr. Greer nor NRDC accepts money from industry sources.

Hattis, Dale: Clark University (Current member, SAB Environmental Health Committee)

Dale Hattis is Research Professor with the Center for Technology Environment and Development (CENTED) of the George Perkins Marsh Institute at Clark University. For the

past twenty-seven years he has been engaged in the development and application of methodology to assess the health ecological and economic impacts of regulatory actions. His work has focused on the development of methodology to incorporate interindividual variability data and quantitative mechanistic information into risk assessments for both cancer and non-cancer endpoints.

Specific studies have included quantitative risk assessments for hearing disability in relation to noise exposure renal effects of cadmium reproductive effects of ethoxyethanol neurological effects of methyl mercury and acrylamide and chronic lung function impairment from coal dust four pharmacokinetic-based risk assessments for carcinogens (for perchloroethylene ethylene oxide butadiene and diesel particulates) an analysis of uncertainties in pharmacokinetic modeling for perchloroethylene and an analysis of differences among species in processes related to carcinogenesis.

He has recently been appointed as a member of the Environmental Health Committee of the EPA Science Advisory Board and for several years he has served as a member of the Food Quality Protection Act Science Review Board. Currently he is also serving as a member of the National Research Council Committee on Estimating the Health-Risk-Reduction Benefits of Proposed Air Pollution Regulations.

The primary source of his recent grant and contract support is the U.S. Environmental Protection Agency.

He has been a councilor and is a Fellow of the Society for Risk Analysis and serves on the editorial board of its journal *Risk Analysis*. He holds a Ph.D. in Genetics from Stanford University and a B.A. in biochemistry from the University of California at Berkeley.

Hoel, David: Medical University of South Carolina (Current member, SAB Environmental Health Committee)

David G. Hoel, Ph.D., is a Distinguished University Professor at the Medical University of South Carolina. Dr. Hoel received his A.B. degree in Mathematics and Statistics from the University of California at Berkeley and his Ph.D. from the University of North Carolina at Chapel Hill and has more than 25 years of experience as a biostatistician, toxicologist and environmental health researcher.

Dr. Hoel's research specialties include: environmental causes of cancer, risk assessment models; statistical and mathematical applications in biology and medicine; epidemiology; and radiation health effects. Dr. Hoel is widely published, having authored or co-authored over 160 journal articles and co-editor of several books and journals. He serves on a variety of national association committees and panels, such as a member of the Institute of Medicine, Agent Orange Committees, EPA's Science Advisory Board.

He is a member of the National Academy of Sciences Institute of Medicine, is a National Associate of the National Academy of Sciences and National Research Council and a Fellow for the American Association for the Advancement of Science. Before joining the faculty at the Medical University Dr. Hoel was a division director at the NIEHS of NIH. This division was made up of four branches with responsibility for the Institute's program in biostatistics, epidemiology and molecular toxicological risk assessment.

Sources of recent grant and/or contract support: include: (1) Savannah River Site Former Production Workers Medical Surveillance Program – Phase II Year Continuation (funded by the

Department of Energy)--the goal of this project is to assess occupational exposures reviewed by former DOE workers at SRS and conduct appropriate medical examinations in order to evaluate work related illness and risk.; (2) "Low Dose Radiation Project" (funded by the Department of Energy, Environmental Biosciences Program); the goal of this project is to develop methods for estimating cancer risks from low dose and low dose rate ionizing radiation; (3)."Radiation Leukemogenesis: Applying Basic Science to Epidemiology Estimates of Low Dose Risks and Dose-Rate Effects"(funded by the Department of Energy)--the goal of this project is to incorporate biological information into mathematical models of radiation induced leukemias; and (4)"Radiation Risk Analysis: Model Issues and Interspecies Extrapolation"(funded by the National Opinion Research Center/NASA)--the goal of this project is to use and evaluate experimental animal data for estimation of human health risks from radiation.

Lambert, George: Robert Wood Johnson Medical School/ University of Medicine and Dentistry of New Jersey (Current member, SAB Environmental Health Committee)

Dr. Lambert is Associate Professor of Pediatrics, Director Division of Pediatric Pharmacology and Toxicology at the University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School – Piscataway/New Brunswick. He is also the Director of the NIEHS/EPA Center for Childhood Neurotoxicology and Exposure Assessment, which is located at the Environmental and Occupational Health Sciences Institute, a jointly sponsored institute of Rutgers, The State University of New NJ and UMDNJ-Robert Wood Johnson Medical School

He holds a B.S. in zoology from University of Illinois, Champaign-Urbana (1968) and an M.D. from the University of Illinois, Chicago, IL (1972).

Recent grants and other outside funding sources include the following: (1) a grant to study the Reproductive Outcomes of the World Trade Center Tragedy (funded by National Institute of Environmental Health Sciences) (2) a grant to determine the influences of environmental exposure to neurotoxicants on child neurological health and development with special emphasis on autism and related disabilities (funded jointly by the National Institute of Environmental Health Sciences and the Environmental Protection Agency) (3) a grant to study the effects of Herbal Phytoestrogens & Prostate Cancer (funded by the Cancer Commission of New Jersey); (4) Effects of eating Crabs with PCBs and Dioxin Laden on Human Health (funded by the New Jersey Department of Environmental Regulations); (5) a grant to study the role of gene polymorphisms in Birth Defects. (funded jointly by the Centers for Disease Control and the NJ State Birth Defects Registry); and (6) the correlation between hypospadism and xenoestrogens (funded jointly by the Centers for Disease Control and the New Jersey Department of Health).

Lemasters, Grace: University of Cincinnati (Current member, SAB Environmental Health Committee)

Dr. Lemasters is a Professor in the Division of Epidemiology and Biostatistics Department of Environmental Health, College of Medicine, University of Cincinnati and former head of Epidemiology and Biostatistics in the Department of Environmental Health, College of

Medicine.

She holds a Ph.D., Department of Environmental Health, College of Medicine, University of Cincinnati, Epidemiology and Environmental Health Science; M.S.N, University of Cincinnati; and a B.S.N., Indiana University.

For almost three decades she has conducted researched in occupational and environmental epidemiology and investigating health effects including ergonomics and musculoskeletal research, respiratory disease, cytogenetic effects, and childhood allergy and asthma. Dr. LeMasters is a national and international expert in occupational and environmental health studies and has published numerous scientific articles and book chapters book in the areas of exposures and health effects and study design methodologies.

She has conducted research on men and women in the military for over 15 years examining the effects of exposures to fuels and solvents on cytogenetics, female hormones, male reproduction and neurological effects. Other areas of research include a 15-year pulmonary longitudinal study of the health effects of refractory ceramic fiber exposure (substitute for asbestos) and lung cancer and lung disease. She has recently received funding as the principle investigator on a 5-year study on diesel exposure and atopy and respiratory disorders in children. Other current research includes the following: caffeine effects on female hormones during early pregnancy, occupational risk factors related to falls, and exposures of women in the military to jet fuel and hormonal changes.

Among her service on Committees and Associations she lists: Federal Advisory Committee on Children's Health NICHD (2002- ); Armed Forces Epidemiological Board (2001-present); Reviewer Department of Defense PRMRP (July 11-13, 2001; Member National Toxicology Program Board of Scientific Counselors of the Office of the Assistant Secretary and Surgeon General (1999-2002); Editorial Board: Occupational and Environmental Medicine (1996-2001); Editorial Board: Journal of Reproductive Toxicology (1991-); Fellow, American College of Epidemiology; Member, Society for Epidemiology Research; and Member: Sigma Theta Tau Alpha and Beta Honors Chapters.

Current sources of recent grant and/or contract support are the: Environmental Protection Agency; NIH-CDC/NIOSH; NIH-NIEHS; and the Refractory Ceramic Fiber Coalition.

Li, Abby: Monsanto Company (Current member, SAB Environmental Health Committee)

Dr. Abby Li received her Ph.D. from the University of Chicago in pharmacology and physiology. She is currently a Senior Science Fellow at Monsanto. She is a toxicologist in the Department of Toxicology and Human Health Risk Assessment. She has specialized expertise in neurotoxicology as well as product stewardship responsibilities involving general toxicology, exposure and risk assessment issues. Dr. Li has conducted numerous studies primarily for regulatory submission in neurotoxicology in adult and developing rats, in humans and in vitro systems.

She was Monsanto's Neurotoxicology Team Leader responsible for developing testing capabilities at Monsanto including motor activity, schedule controlled operant behavior, functional observational battery, auditory startle habituation, learning and memory and neuropathology. She has also conducted *in vivo* pharmacokinetic studies (ADME studies) and *in vitro* metabolism studies. Dr. Li served on the Editorial Board of *Neurotoxicology* from 1995-2001.Dr. Li was invited by the US EPA country representative to serve on the US team of

experts to develop international OECD guidelines on neurotoxicity (1995 - 1998) and developmental neurotoxicity (1996-2000). Dr. Li is the Chair of the Neurotoxicology Technical Panel of the American Chemistry Council's Long Range Initiative (ACC LRI) responsible for funding research to advance the field of neurotoxicology in focus areas such as susceptible populations, and in developing new methods for hazard and exposure assessment. She served as Co-Chair of Crop Life America's Developmental Neurotoxicology Working Group in 2000 and is currently a member of this group. She is a member of the EPA's Science Advisory Board's Environmental Health Committee and reviewed the EPA's 1999 draft cancer guidelines, the RfC Methods Case Studies, and the Lead 403 Rule among other documents. Dr. Abby Li was a peer consultant to the September 10-11, 1996 EPA Benchmark Dose Peer Consultation Workshop

Luderer, Ulrike: University of California at Irvine (Current member, SAB Environmental Health Committee)

Dr. Ulrike Luderer is Assistant Professor of Medicine in the Division of Occupational and Environmental Medicine at the University of California at Irvine. She also holds joint appointments in the Departments of Developmental and Cell Biology and Environmental Toxicology. Dr. Luderer's research focuses on mechanisms of action of reproductive toxicants and on protective mechanisms against those toxicants. She is a recipient of a National Institute of Environmental Health Sciences research grant (2002-2007) entitled "Glutathione:Protecting Ovarian Follicles from Oxidant Injury" and a co-investigator on an EPA grant "Latent Effects of Gestational Exposure to Heptachlor" She has published peer-reviewed journal articles and book chapters and presented research at national and international scientific conference on such topics as the effects of toluene exposure on reproductive endocrine function, the functions of and regulation of glutathione in the ovary, the differential regulation of follicle-stimulating hormone and luteinizing hormone secretion, and reviews of reproductive and developmental and endocrine toxicology. She has served on the National Toxicology Program/NIEHS Center for the Evaluation of Risks to Human Reproduction Expert Panel on 1- and 2-Bromopropane and on the National Research Council subcommittee on methyl bromide. She is currently member of the EPA SAB's Environmental Health Committee. Dr. Luderer has a Ph.D. in reproductive endocrinology and an M.D. from Northwestern University and is board-certified in Internal Medicine and in Occupational and Environmental Medicine. She has a Sc.B. in biomedical engineering from Brown University.

McClain, Michael: McClain Associates

Dr. R. Michael McClain is currently an Adjunct Professor University of Medicine and Dentistry of NJ and now works primarily as a consultant in toxicology. He was formerly a Distinguished Research Leader and Director of Toxicology, Hoffmann-La Roche, Inc. Dr. McClain received his Ph.D. from the Department of Pharmacology at the University of Iowa and B.S. and M.S. degrees from Duquesne University. Dr. McClain is a Diplomate of the American Board of Toxicology and a Fellow of the Academy of Toxicological Sciences. He has worked in the pharmaceutical industry for over 30 years in the areas of teratology and reproductive toxicology, general toxicology and carcinogenicity testing. His research activities are involved

primarily in mechanisms of chemical carcinogenesis for thyroid, liver and adrenal and regulatory aspects for cancer risk assessment. He has been active in the Pharmaceutical Research and Manufactures Association and PhRMAs efforts on harmonizing international guidelines for drug development (ICH). He has been involved with the ILSI organization and served as President of the ILSI's Health and Environmental Science Institute (HESI) and as a member of ILSI's Board of Trustees. Dr McClain is a member of the National Advisory Environmental Health Sciences Council for NIEHS. Dr. McClain is also active in the Society of Toxicology having served a term as Treasurer and as President of the Society in 1998

Melnick, Ronald: National Institute of Environmental Health Sciences

Dr. Melnick is a Senior Toxicologist and Director of Special Programs in the Environmental Toxicology Program at the National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health in Research Triangle Park, North Carolina. Prior to this position he was Group Leader of the Toxicokinetic and Biochemical Modeling Group in the Laboratory of Computational Biology and Risk Analysis at NIEHS. Dr. Melnick obtained his B.S. degree from Rutgers University and his Ph.D. in food science/biochemistry from the University of Massachusetts at Amherst. He was a postdoctoral research fellow in the Department of Physiology-Anatomy at the University of California in Berkeley and then an assistant professor of life sciences at the Polytechnic Institute of New York. At NIEHS he has been involved in the design, monitoring and interpretation of NTP toxicity and carcinogenesis studies, as well as mechanistic studies to characterize the behavior of environmental carcinogens. He spent one year as an agency representative to the White House Office of Science and Technology Policy to work on interagency assessments of health risks of environmental agents and on risk assessment research needs in the Federal government. Dr. Melnick has organized several national and international symposiums and workshops on health risks associated with exposure to environmental and occupational toxicants. He has also served on numerous scientific review and advisory panels, including the working group of the International Agency for Research on Cancer (1995) that classified trichloroethylene as probably carcinogenic to humans. Dr. Melnick has served on several committees at NIEHS, including Chair of the Toxicokinetic Faculty and member of the NIEHS review group for the NTP Report on Carcinogens. The latter group reviewed data on trichloroethylene for listing in the Report on Carcinogens. Dr. Melnick is a Fellow of the Collegium Ramazzini. As a federal employee, he does not receive any grant or contract support.

Mirer, Franklin E.: International Union, UAW

Franklin E. Mirer is a toxicologist and certified industrial hygienist. His primary scientific interest is exposure assessment in the occupational environment. Dr. Mirer serves as Director of the UAW Health and Safety Department. This technical unit coordinates the activities of the UAW in Occupational Health and Safety, and provides policy advice to the union's officers, assists with collective bargaining, conducts plant inspections, reviews technical and statistical data for all levels of the union, designs and delivers training programs, represents the union before administrative agencies and professional bodies and conducts occupational

safety and health research. The Department administers training grants from NIEHS and OSHA. Dr. Mirer has participated in each round of automobile industry collective bargaining since 1976. Dr. Mirer received a Ph.D. in organic chemistry from Harvard University in 1972, and trained further as a Research Fellow in Toxicology at the Harvard School of Public Health. He joined the UAW staff in 1975 and was named Director of the Health and Safety Department in 1982.Dr. Mirer serves on the NIOSH National Occupational Health Research Agenda liaison committee. He served on the OSHA Metalworking Fluid Standards Advisory Committee, the Institute of Medicine Roundtable on Environmental Health Sciences Research and Training, the National Academy of Sciences Committees on Institutional Means for Risk Assessment, Risk Assessment Methodology, and the Review of the Health Effects Institute, an IARC Working Group, the CDC Injury Advisory Committee and the NIH Safety and Occupational Health Study Section. Dr. Mirer developed and delivered testimony before OSHA regarding a dozen health and safety standards, and has testified before House and Senate Committees on occupational safety and health and regulatory policy matters, including ergonomics. He served on the Board of Scientific Counselors of the National Toxicology Program, and its Report on Carcinogens Review Sub-committee. Dr. Mirer was a member of an IARC Monograph Working Group. He has co-authored scientific papers in exposure assessment, risk assessment and epidemiology. Dr. Mirer is a member of the National Safety Council's Health and Safety Hall of Fame, and is a Fellow of the Collegium Ramazzini and the American Industrial Hygiene Association. He also holds appointments as an Adjunct Associate Professor at the Michigan School of Public Health, and Visiting Lecturer at the Harvard School of Public Health.

David Ozonoff: Boston University

David Ozonoff received his bachelor's degree in mathematics from the University of Wisconsin in 1962 and his M.D. degree from Cornell University Medical College in 1967. In 1968 he received an M.P.H. degree from Johns Hopkins School of Hygiene and Public Health. He then pursued research work at MIT from 1968 to 1977, studying, among other things, the psychophysical difficulties of radiologists when reading chest x-rays. He and his colleagues also published one of the first two-dimensional x-ray reconstructions (CAT scans) in the literature in 1969. He also served as a consultant to the World Health Organization, assisting WHO in the preparation and writing of its contribution to the first International Conference on the Environment which took place in Stockholm in 1972. In 1975 he was a Macy Fellow in the History of Medicine and the Biological Sciences at Harvard, and in 1976 a Mellon Fellow in the History of Public Health at MIT.

In 1977 he moved to the Boston University School of Public Health and in 1983 he became the Chair of the Department of Environmental Health, a position he still holds. He is Professor of Public Health at Boston University School of Public Health, and Professor of Sociomedical Sciences and Community Medicine at Boston University School of Medicine. He directs the Superfund Basic Research Center at Boston University.

Dr. Ozonoff's research has centered on epidemiological studies of populations exposed to toxic agents, especially the development of new methods to investigate small exposed populations. He has studied populations around Superfund sites in a number of places, most

recently a very large cancer case control study in the Upper Cape region of Massachusetts involving exposure to PCE. Dr. Ozonoff frequently serves as advisor or consultant to local, state and federal agencies on matters of health effects from hazardous wastes and contaminated drinking water. He is the author of numerous scientific articles and is on the editorial boards of the *Archives of Environmental Health*, *American Journal of Industrial Medicine*, *The Journal of Urban Health*, and is the North American Editor-in-Chief of the new online journal, *Environmental Health*. He is a Fellow of the Johns Hopkins Society of Scholars and a Fellow of The Collegium Ramazzini.

Solomon, Gina: Natural Resources Defense Council

Dr. Gina Solomon is a Senior Scientist at the Natural Resources Defense Council in San Francisco and an Assistant Clinical Professor of Medicine at the University of California at San Francisco. Dr. Solomon is a specialist in internal medicine, preventive medicine, and occupational and environmental medicine. Her work has focused on environmental and occupational threats to reproductive health and child development. She attended medical school at Yale and underwent post-graduate training in medicine and public health at Harvard.. Dr. Solomon served on the U.S. EPA's Federal Advisory Committee on endocrine disrupting chemicals and is a scientific advisor to numerous organizations including the California Department of Health Services Environmental Epidemiology Section and the Pediatric Environmental Health Specialty Unit at U.C. San Francisco. Dr. Solomon has published peer-reviewed articles on various topics, including solvents and miscarriage, endocrine disruptors, diesel exhaust and asthma, and contaminants in breast milk. She is a co-author of the book, Generations at Risk: Reproductive Health and the Environment, published by MIT Press in 1999.

Wallinga, David: Institute for Agriculture and Trade Policy

David Wallinga, M.D., MPA is a physician, and has been Senior Scientist and Co-director of the Food and Health Program at the non-profit Institute for Agriculture and Trade Policy (IATP), in Minneapolis since September 2000.Previously, he worked for 3 years as Senior Scientist in the Public Health Program of the Natural Resources Defense Council in Washington, D.C. Dr. Wallinga holds a medical degree from the University of Minnesota, a Masters in Public Affairs from Princeton University, and a B.A. from Dartmouth College. His areas of expertise include risk assessment and regulation of toxic chemicals including pesticides; food and drinking water routes of exposure to toxic chemicals; health impacts of pesticides and other neurodevelopmental toxicants on fetuses and children; agricultural antibiotics and their contribution to antimicrobial resistance; and the application of the precautionary principle in regulation. He is author of *Putting Children First: Making Pesticide Levels in Food Safer for Infants& Children*, co-author of several journal articles on pesticide regulations it pertains to children's health, and a contributing author to *In Harm's Way: Toxic Threats to Child Development.*. Dr. Wallinga serves on the Integrated Human Exposure Committee of the EPA Science Advisory Board, is a board member of the Science Environment Health Network, and has served in various leadership capacities of the Environment Section of the American Public

Health Association. In 1995-96, he was granted a Science Diplomacy Fellowship at the U.S. Agency for International Development by the American Association for the Advancement of Science. Dr. Wallinga previously worked as a consultant and health economist to the World Health Organization and the World Bank. Dr. Wallinga's work at IATP is funded by the Bush Foundation, the Minneapolis Foundation, the Bauman Foundation, the Homeland Fund, and various other foundations.

Whyatt, Robin: Columbia University

Dr. Robin Whyatt is Deputy Director of the Columbia Center for Children's Environmental Health and is Assistant Professor in the Department of Environmental Health Sciences at the Mailman School of Public Health, Columbia University. Dr. Whyatt's research focus is on the effects of environmental exposures on women and children, including the developing fetus. Prior to coming to Columbia in 1991, she evaluated the extent of pesticide exposure in the preschooler's diet as Senior Staff Scientist at the Natural Resources Defense Council (NRDC). Her research at Columbia University has used biologic markers to study effects of environmental exposures during pregnancy. This has included a molecular epidemiologic study of prenatal exposures to ambient air pollution and cigarette smoking in Poland. Dr. Whyatt's is currently collaborating on a comprehensive community-based study of environmental risks to African American and Dominican mothers and newborns in Northern Manhattan and the South Bronx. The prospective cohort study is evaluating effects of environmental exposures on fetal growth, neurocognitive developmental and asthma risk. Dr. Whyatt's focus is on the extent of exposure to non-persistent pesticides (organophosphates, carbamates and pyrethroids) during pregnancy among this minority population. Dr. Whyatt is also collaborating with the Center for Disease Control on the validation of biomarkers of exposure to contemporary-use pesticides during pregnancy. Dr. Whyatt has published widely on the application of biologic markers to studies of environmental risks to infants and children and on the effects of environmental exposures during fetal development. She is currently principal investigator on three grants: a U.S. EPA STAR grant to validate the measurement of non-persistent pesticides in postpartum meconium as a biomarker of fetal exposure; a NIEHS RO1 grant to validate a battery of biomarkers of prenatal exposure; and on an intervention grant from the Speaker's Fund for Public Health Research to reduce residential pesticide exposures during pregnancy. Dr. Whyatt served on the U.S. EPA Workshop, Critical Windows of Exposure for Children's Health, and on the U.S. EPA Workshop, Technical Workshop on Issues Associated with Considering Developmental Changes in Behavior and Anatomy when Assessing Exposure to Children. She was Co-chair of the Symposium on Alternative Human Matrices for Biomonitoring, at the 2001 International Agency for Exposure Assessment, Charleston, South Carolina and is currently serving on the Exposures to Chemical Agents Work Group of the National Children's Longitudinal Cohort Study. Dr. Whyatt received her Doctorate in Public Health (Dr.P.H.) from Columbia University with honors in 1995 and her Masters in Public Health (M.P.H) from Columbia University in 1985.

Yang,Raymond: Colorado State University,

Raymond S. H. Yang is presently Professor of Toxicology and Director of Center for Environmental Toxicology and Technology, one of 14 Programs of Research and Scholarly Excellence at Colorado State University (CSU). Between July 1990 and June 1995, Dr. Yang served as the Head, Department of Environmental Health, College of Veterinary Medicine and Biomedical Sciences, CSU, Fort Collins, CO. Prior to joining CSU in 1990, Dr. Yang spent seven years each in chemical industry (Bushy Run Research Institute, Union Carbide - Mellon Institute, 1976 - 1983) and in the federal government [National Institute of Environmental Health Sciences/National Toxicology Program (NIEHS/NTP), 1983 - 1990].

Dr. Yang received his B.S. in Biology from the National Taiwan University in 1963; M.S. and Ph.D. in Toxicology/Entomology from North Carolina State University in 1967 and 1970, respectively. Between 1970 and 1973, he was a postdoctoral fellow at Cornell University. Between 1973 and 1976, he was Research Associate and then Assistant Professor at the Institute of Comparative and Human Toxicology, Albany Medical College. Dr. Yang had also been appointed Adjunct Associate Professor at University of Pittsburgh and Adjunct Professor at North Carolina State University.

Dr. Yang's research expertise and interests cover many subdisciplines in toxicology, including toxicology of chemical mixtures, toxicologic interactions, physiologically based pharmacokinetic/pharmacodynamic (PBPK/PD) modeling, biologically based dose-response (BBDR) modeling, carcinogenesis and neuro-developmental toxicology. Between 1992 and 2000, he served as the Program Director of the NIEHS Superfund Basic Research Program Project at CSU and since the summer of 1999 he has been the Program Director for an NIEHS Quantitative Toxicology Training Grant. Since 1990, Dr. Yang has been developing an interdisciplinary research program on Quantitative and Computational Toxicology using the central theme of PBPK/PD, BBDR, and reaction network modeling of chemicals and chemical mixtures at CSU.

Dr. Yang's committee work includes serving as a Committee or Expert Panel Member for the following Committee/Panel or organizations: National Academy of Sciences/National Research Council Safe Drinking Water Subcommittee on Mixtures; USEPA/Environmental Criteria Assessment Office (ECAO); Screening and Testing Work Group of the Endocrine Disruptor Screening and Testing Advisory Committee, USEPA; Electric Power Research Institute (EPRI); Expert Panel Member, Risk Assessment for Mixtures of Drinking Water Disinfection-Byproducts, International Life Sciences Institute/USEPA; Institute of Medicine, National Academy of Sciences Committee to Study the Interactions of Drugs, Biologics, and Chemicals in Deployed U. S. Military Forces; Chair for a Chemical Mixture Workshop Agency for Toxic Substances and Disease Registry (ATSDR); Health Council of the Netherlands; Society of Toxicology Expert Panel on Chemical mixtures; Chemical Mixture Committee member to National Occupational Research Agenda, NIOSH; and NIEHS Environmental Health Sciences Review Committee. Dr. Yang's research support came principally from the National Institute of Health (NIH), U.S. Air Force, U.S. Environmental Protection Agency (EPA), ATSDR, and Center for Disease Control and Prevention (CDC)/National Institute of Occupational Safety and Health (NIOSH).

Attachment 3: List of the Names of Groups and Individuals Submitting Public Comment on the TCE Short List

1. Carl F. Cranor, Professor of Philosophy, Fellow, American Association for the Advancement of Science, University of California

2. Keith Storey, Berkeley, CA

3. Jennifer Sass, Ph.D., Senior scientist, Natural Resources Defense Council

4. Raymond B. Ludwiszewski, Gibson, Dunn & Crutcher LLP, representing Lockheed Martin Corporation

5. Paul H. Dugard, PhD, Director of Scientific Programs, Halogenated Solvents Industry Alliance, Inc

Attachment 4: Questions Posted to Short List Candidates about Their "Points of View" and Relationship to the Review Material to Be Considered by the Panel

1. Have you had any previous involvement with the review document(s) under consideration, including authorship, collaboration with the authors, or previous peer review functions? If so, please identify that involvement.

2. Have you served on previous advisory panels or committees that have addressed the topic under consideration? If so, please identify those activities.

3. Have you made any public statements (written or oral) on the issue? If so, please identify those statements.

4. Have you made any public statements that would indicate to an observer that you have taken a position on the issue under consideration? If so, please identify those statements.

Attachment 5

# U.S. Environmental Protection Agency
# Science Advisory Board
# Environmental Health Committee
# Trichloroethylene Health Risk Assessment:
# Synthesis and Characterization Review Panel *

2002

**CHAIR**

**Dr. Henry Anderson**, Chief Medical Officer, Division of Public Health, Wisconsin Division of Public Health, Madison, WI

Also Member: Integrated Human Exposure Committee
Executive Committee

**EHC MEMBERS**

**Dr. Paul Foster**, Independent Consultant, Endocrine, Reproductive and Developmental Toxicology, Apex, NC

**Dr. Dale Hattis**, Research Professor, Center for Technology, Environment, and Development, Marsh Institute, Clark University, Worcester, MA

**Dr. David Hoel**, Distinguished University Professor , Department of Biometry and Epidemiology, Medical University of South Carolina, Charleston, SC

**Dr. George Lambert**, Associate Professor and Center Director, Center for Child and Reproductive Environmental Health, Environmental and Occupational Health Sciences Institute, Robert Wood Johnson Medical School/ University of Medicine and Dentistry of New Jersey, Piscataway, NJ

**Dr. Grace Lemasters**, Professor, Division of Epidemiology and Biostatistics, University of Cincinnati, Cincinnati, OH

**Dr. Abby Li**, Senior Neurotoxicologist, Human Healtn and Risk Assessment Department, Monsanto Company, St. Louis, MO

**Dr. Ulrike Luderer**, Assistant Professor , Department of Medicine, Center for Ocupational and Environmental Health, University of California at Irvine, Irvine, CA

**CONSULTANTS**

**Dr. Susan J. Borghoff**, Staff Scientist, Division of Biological Sciences, CIIT Centers for Health Research, Research Triangle Park, NC

**Dr. Lutz Edler**, Head of Biostatistics Unit, Research Programme in Genome Resesarch and Bioinformatics, German Cancer Research Center, Heidelberg, Germany

**Dr. Michael McClain**, Consultant in Toxicology, McClain Associates, Randolph, NJ

**Dr. Gina Solomon**, Senior Scientist, Natural Resources Defense Council, San Francisco, CA

**Dr. Robin Whyatt**, Assistant Professor of Clinical Sociomedical Science, Columbia University , New York, NY

**Dr. Raymond Yang**, Director, Center for Environmental Toxicology and Technology, Colorado State University, Fort Collins, CO

**FEDERAL EXPERTS**

**Dr. Aaron Blair**, Chief, Occupational Epidemiology Branch, National Cancer Institute, National Institutes of Health, Bethesda, MD

**Dr. Ronald Melnick**, Director of Special Programs, Environmental Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, NC

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* Members of this SAB Panel consist of

a. SAB Members: Experts appointed by the Administrator to serve on one of the SAB Standing Committees.

b. SAB Consultants: Experts appointed by the SAB Staff Director to a one-year term to serve on ad hoc Panels formed to address a particular issue.

c. Liaisons: Members of other Federal Advisory Committees who are not Members or Consultants of the Board.

d. Federal Experts:"Federal Experts" are federal employees who have technical knowledge and expertise relevant to the subject matter under review or study by a particular panel.